DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

March 20, 2003

VIA FEDERAL EXPRESS

Ricky A. Ellis
414 Lee Osborne Road
Lansing, NC 28643

Warning Letter
03-ATL-15

Dear Mr. Ellis:

An investigation at your cattle farm located at Lansing, North Carolina, conducted by FDA investigator, Edward Deberry, on January 27, 2003, confirmed that in September 2002 you offered a cow for sale for slaughter for human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigation also revealed you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about September 9, 2002, you sold a cow, identified with back tag numbe[redacted][1], to [redacted] for slaughter as human food. USDA analysis of tissue samples collected from this cow identified the presence of the drug sulfamethazine at a level of 37.49 parts per million (ppm) in the liver and 26.79 ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Section 556.670). The presence of this drug, at levels above the tolerance, in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that could allow medicated animals, bearing potentially harmful drug residues, to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. As noted in the Form FDA 483, issued to you on January 27, 2003, you failed to maintain treatment records for a sick cow, including dates of administration, dosage, drug, and withdrawal times. Food from animals held under such conditions is adulterated under Section 402(a)(4) of the Act.

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[1] The back tag number was assigned to the cow by [redacted] upon receipt.

In addition, you caused the drug *SUSTAIN III*, containing sulfamethazine, which your farm uses on cows, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Your use of this drug in cattle without following the labeled withdrawal period causes the drug to be unsafe to use.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your cattle farm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in enforcement action being initiated by the FDA without further notice such as seizure and/or injunction.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within fifteen (15) days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Carlos A. Bonnin, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Diane L. Todd-Murrell

for Mary H. Woleske, Director
Atlanta District